DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

95112d

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WARNING LETTER

NWE-02-05W

FEDERAL EXPRESS

November 2, 2004

Hans B.R. Sigvardsson, President and Owner
Liko, Inc.
842 Upper Union Street, Suite 4
Franklin, MA 02038

Dear Mr. Sigvardsson:

During an inspection of your establishment located in Franklin, Massachusetts, on July 28 and 29, 2004, an investigator from the U.S. Food and Drug Administration (FDA) determined that your firm is the importer/initial distributor of the Golvo patient lifts manufactured by Liko AB, Lulea, Sweden. These products are devices within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements for medical devices, which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to maintain complaint files and failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit, as required by 21 CFR 820.198(a). For example:

   a. The firm has no written complaint handling procedures.
   b. No documentation was found regarding two incidents where patients fell because the actuators on the patient lifts bent.

2. Failure to review, evaluate, and investigate any complaint involving the possible failure of a device to meet any of its specifications, and failure of a designated individual to review, evaluate, and investigate any complaint that represents an event that must be reported to FDA under 21 CFR Part 803, as required by 21 CFR 820.198(c) and (d). For example:

   a. There is no documentation of any follow-up investigation or of any notification to either FDA or the foreign manufacturer of a complaint involving a Golvo patient lift with a strap that slipped out, resulting in a patient fall to the floor.
   b. There is no documentation of any follow-up investigation or of any notification to either FDA or the foreign manufacturer of a complaint involving injuries with two different patient lifts. One injury involved a Uno Lift that tipped, resulting in a concussion to the caregiver. The other injury involved a Sabina Lift, but did not list any other details.
   c. There is no documentation of any follow-up investigation or of any notification to either FDA or the foreign manufacturer of a complaint involving two instances of a piece of a lift that broke, resulting each time in the patients being dropped to their beds.
   d. There is no documentation of the follow-up investigation or of the firm's president's visit to the site for a complaint involving a problem with the lift strap and the patient being dropped to the floor.
   e. There is no documentation of any follow-up investigation or of any notification to either FDA or the foreign manufacturer of a complaint involving a lift with a safety strap buckle that broke.
   f. There is no documentation of any notification to either FDA or the foreign manufacturer of a complaint involving a Sabina patient lift, which would not stop lifting, resulting in the patient hitting his or her head. The firm had a copy of a MedWatch report written by the customer and forwarded with notes from the distributor. The April 17, 2001 notes attached to this May 1, 2001 MedWatch report describe a similar incident, which resulted in a patient breaking a shoulder. There is no documentation of any notification to either the FDA or the foreign manufacturer of the second incident.
   g. There is no documentation of any notification to either FDA or the foreign manufacturer of a complaint involving four patient falls from patient lifts.
   h. There is no documentation of any follow-up investigation or of any notification to either FDA or the foreign manufacturer of a complaint involving a patient who fell out of a Golvo patient lift.

3. Failure to adequately establish procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22.

Additionally, the above-stated inspection revealed that your devices are misbranded under section 502(t)(2) of the Act, in that your firm failed or refused to furnish any material or information required by or under section 519 respecting the device. Significant deviations include, but are not limited to, the following:

21 CFR Part 803 - Medical Device Reporting (MDR)

1. Failure to submit an MDR report within the 30 day time frame, as required by 21 CFR 803.50(a)(1). For example, on July 4, 2004, a patient fell to the floor after the quick release hook failed on a Golvo 7000ES patient lift, and the patient subsequently died later that day. No MDR report was submitted for this incident.

2. Failure to conduct and document an investigation of an event, as required by 21 CFR 803.50(b)(2). For example, your firm received a complaint involving two incidents in November of 2002, in which the quick release hooks broke and the patients fell to their beds. There is no documentation of an investigation into these incidents.

21 CFR Part 806 - Corrections and Removals (CAR)

Failure to include in the record a justification for not reporting a correction or removal action to FDA, including conclusions and follow-ups, that was reviewed and evaluated by a designated person, as required by 21 CFR 806.20(b)(4). For example, there were no written justifications for not reporting to FDA a product removal conducted on the Golvo 7007ES patient lifts. The product removal involved [redacted] units that had been manufactured with actuators that had only one side of the friction washer greased, which could result in a jamming mast. A June 27, 2002 notification was faxed to distributors, stating that the actuators should be returned to your company for greasing and rebuilding. In addition, the above-stated inspection revealed that you failed to develop written MDR procedures, as required by 21 CFR 803.17. For example, your firm lacks MDR procedures, definitions of MDR reportable events, instructions listing information to be obtained, evaluated, and forwarded, and instructions stating where and when to forward the information.

We received your response dated August 16, 2004, concerning our investigator's observations on the FDA Form 483. We have reviewed your letter and have concluded that your response is inadequate in that you have not yet implemented corrective actions, although you have promised to do so at a later date.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating

and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your quality system.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering award of contracts. Additionally, no premarket approval applications for devices to which the Quality System regulation deficiencies are reasonably related will be approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties.

Please notify this office in writing within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Bruce R. Ota, Compliance Officer, Food and Drug Administration, One Montvale Avenue, 4th Floor, Stoneham, Massachusetts 02180.

Sincerely yours,

Gail T. Costello
District Director
New England District